K024251

510(K) SUMMARY
SightFix

MAR 1 8 2003

I. Submitter:

WORLD OF MEDICINE Lemke GmbH
Danziger Strasse 21
82194 Gröbenzell
Germany

II. Device Names:

1.	Classification Name:	Endoscope and Accessory
2.	Common or Usual Name:	Laparoscope and Endoscope Holder
3.	Proprietary Name:	SightFix

III. Classification:

Class II. The device is described in 21 C.F.R. § 876.1500. The product code for the device is GCJ.

IV. Predicate Device:

- **MGB LAPALUX Telescope** (K982013) manufactured by MGB Endoskopische Geräte GmbH
- **Robotrac ™ Retractor Arm (Unitrac)** (K893121) manufactured by Aesculap Instruments Corp.
- **KSEA Endoscope Holder** (K990334) manufactured by Karl Storz Endoscopy-America, Inc.

V. Intended Use:

The SightFix is intended to allow access and observation of body cavities and the surgical field during diagnostic and therapeutic procedures in laparoscopy and open surgery.

VI. Device Description:

The SightFix consists of a rigid endoscope and a flexible holding arm. The rigid endoscope of the SightFix contains an optic and a light fiber. The SightFix endoscope is designed to be used with the camera SightCam and the light source SightLight manufactured by WORLD OF MEDICINE Lemke GmbH. In addition, the use of adapters allows an easy attachment of standard 180W endoscopic light sources (halogen, xenon, quartz) to the endoscope. The holding arm of the SightFix is a manually operated endoscope holder to ensure an optimal positioning of the endoscope. Both the rigid endoscope and some components of the holding arm are autoclavable.

VII. Substantial Equivalence:

The SightFix described in this notification is similar in intended use, design, material and technological characteristics to the MGB LAPALUX Telescope (K982013) manufactured by MGB Endoskopische Geräte GmbH, the Robotrac ™ Retractor Arm (Unitrac) (K893121) manufactured by Aesculap Instruments Corp. and the KSEA Endoscope Holder (K990334) manufactured by Karl Storz Endoscopy-America, Inc.

Both the endoscope of the SightFix and the predicate device MGB LAPALUX Telescope (K982013) are intended to allow access and observation of body cavities during diagnostic and therapeutic procedures in laparoscopy. In addition, both devices are rigid and autoclavable.

The holding arm of the SightFix and the predicate devices Robotrac ™ Retractor Arm (Unitrac) (K893121) and KSEA Endoscope Holder (K990334) are devices all intended to hold an endoscope during diagnostic and therapeutic endoscopic procedures. Moreover, the SightFix holding arm and the Robotrac ™ Retractor Arm (Unitrac) (K893121) are both intended to be used during open surgery. All three devices contain stainless steel and aluminum and can be sterilized.

The differences between the SightFix and the predicate devices are minor and raise no new questions of safety and effectiveness. Accordingly, WORLD OF MEDICINE Lemke GmbH believes that the SightFix is substantially equivalent to the predicate devices currently on the market.

VIII. Performance Data:

The device complies with the International standards IEC 60601-2-18:1996 (Particular requirements for the safety of endoscopic equipment). Some Components of the SightFix comply with the European Standards EN 554:1994, EN 556:2001-01 and EN 1174-1:1996 (Sterilization of Medical Devices). In addition, the device bears the CE mark in accordance with the European Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2003

World of Medicine Lemke GmbH
c/o Ms. Susanne Raab
91 Trowbridge Street
Cambridge, Massachusetts 02138

Re: K024251
Trade/Device Name: SightFix
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 13, 2002
Received: December 23, 2002

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: WORLD OF MEDICINE Lemke GmbH

510(K) NUMBER (if known): K024251

DEVICE NAME: SightFix

INDICATIONS FOR USE:

The SightFix is intended to allow access and observation of body cavities and the surgical field during diagnostic and therapeutic procedures in laparoscopy and open surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024251